

REMARKS

Reconsideration of the present application is requested. In this response, Applicants have amended claim 15 to incorporate the limitations of dependent claim 20, which has thus been cancelled. Applicants have also amended claim 10 to change its dependency to avoid a potential antecedent basis problem.

An earlier indication of allowability of claims 15-19 was withdrawn in a prior non-final Office Action. Applicant successfully traversed the new ground of rejection interposed in that Office Action. However, in the present non-final action, new grounds for rejection of all the pending claims have been presented.

In particular, claims 8-13 and 15-19 have been rejected as obvious over the combination of Person (5,997,552) and DiGiovanni (4,478,220). The Person reference was alleged to disclose every limitation of independent claim 15 except for the "means for preventing retrograde movement." The DiGiovanni reference was recited as disclosing structure operable to prevent backwards movement.

The Person reference fails to disclose additional elements of claim 15 other than just the "means" clause element. In particular, claim 15 defines an introduction end of the track assembly configured to receive wafers and a first track defining a wafer channel having an opening at the introduction end configured to receive wafers therethrough. As shown in FIGS. 5 and 8-10 of Person, the device includes a series of fasteners 31 that are pre-loaded into the track 73 and situated at the discharge end of the track. As shown in the build-up drawings of FIGS. 8-10, the pre-loaded fasteners are encased at least by the cover plate 90, leaf spring 94 and upper housing 70. Thus, the track assembly in the Person device is not capable of introduction of the fasteners, or a wafer for that matter. The Person device certainly does not disclose any opening into a wafer channel at the introduction end of the track assembly, as recited in Applicants' claim 15.

The DiGiovanni reference suffers from the same deficiency. In that reference, the clips 11 are pre-loaded into the fixed rack 130 (FIG. 2; col. 13, lines 27-29). A moving rack 120 snaps over the fixed rack to enclose the clips (col. 13, lines 12-17), and the entire pre-loaded cartridge is snapped into channel

8 on the scissors tool (col. 12, lines 25-27). While the clips 11 are positioned along the length of the fixed rack, all of the clips are pre-loaded so there is no "wafer channel opening" that is disclosed or even necessary in the DiGiovanni device. Thus, neither Person nor DiGiovanni, alone or in combination, disclose every limitation of independent claim 15, each lacking the wafer channel opening defined in that claim.

Moreover, neither reference contemplates a device in which the respective fasteners 31 (Person) and clips 11 (DiGiovanni) are not pre-loaded or in which the respective clips and fasteners are introduced through an opening into the track assembly channel. As shown in FIG. 1 of Person, the entire device is closed, with no access to the fasteners 31 inside until they are discharged from the end of the body portion 14. Likewise, as shown in FIGS. 7-9 of Person, the clips 11 are trapped within the track assembly and inaccessible until they are discharged into the ligating jaws 16 (col. 15, lines 44-57).

In addition to this deficiency, the cited references also lack a cartridge, as added to claim 15 by amendment. This limitation was imported from dependent claim 20, which has been cancelled. It is noted that claim 20 had been rejected as obvious over the combination of Person and DiGiovanni, and with the additional reference of Woods (5,190,560). Woods was cited as disclosing a cartridge coupled to a track assembly. It was alleged that it would have been obvious to "manufacture the device of Person modified by DiGiovanni further comprising a cartridge in view of Woods in order to provide the device with enough elements to complete a surgical procedure without having to refill the device." This rationale does not take proper account of the disclosure of the three cited references.

Both Person and DiGiovanni disclose devices in which the fasteners or clips are pre-loaded within the track assembly. In fact, DiGiovanni refers to the pre-loaded track assembly as a cartridge capable of applying multiple clips. See, e.g., the Abstract of DiGiovanni. This cartridge is removably mounted in a "cartridge-receiving channel" on the clip applier. See, FIG. 6; col. 14, lines 25-27. Thus, both Person and DiGiovanni disclose a device "with enough elements

to complete a surgical procedure without having to refill the device." Consequently, there would be no motivation for a person of ordinary skill to add yet another cartridge to the cartridge that already exists on the respective devices.

Furthermore, both Person and DiGiovanni disclose fasteners or clips that are not susceptible to dispensing from a cartridge in the manner shown in Woods. In Person, the meniscal fasteners 30 include two anchor members 120 coupled by a flexible member 124. See, Person, FIG. 16; col. 7, lines 47-67. The presence of the flexible link 124 renders an approach like that shown in Woods untenable. As a person of ordinary skill in this art would recognize, the nature of the fasteners 30 requires the pre-loaded track approach utilized in the Person device. This person of ordinary skill would not be motivated to alter this approach by providing a separate cartridge attachment in the form of the Woods device.

The same rationale applies to the DiGiovanni reference. The ligating clips 11 in DiGiovanni are, by necessity and design, bendable so that they can be clamped around a desired blood vessel. See, DiGiovanni, col. 6, lines 40-45. The entire advancement mechanism in this reference is configured to support each clip as it travels toward the ligating jaws so that the clips do not bend or deform within the cartridge. Again, a person of ordinary skill in this art would recognize that the nature of the ligating clips 11 requires the pre-loaded cartridge approach utilized in the DiGiovanni device. This person of skill would certainly not be motivated to alter that approach or to provide a separate cartridge, like that in Woods, attached to the existing pre-loaded cartridge.

Finally, in both references, the devices being discharged (i.e., the fasteners 30 of Person and the clips 11 of DiGiovanni) are small enough to be pre-loaded into an advancement track assembly. Since the size of these elements permits pre-loading, as disclosed in Person and DiGiovanni, there is no motivation to alter either device to incorporate a separate cartridge as well as any additional mechanism necessary to strip successive elements from the cartridge. In contrast, the present invention contemplates dispensing wafers which do not

lend themselves to pre-loading, otherwise the track assembly would have to be significantly longer than disclosed in the present application.

Claim 15 further requires that the claimed cartridge be coupled to the track assembly at the opening to the wafer channel. This wafer channel opening is at the introduction end of the track assembly, at the opposite end of the track from the discharge end. As explained above, neither Person nor DiGiovanni include an accessible "wafer channel opening". In Person, the proximal end of the track is enclosed within the shell of the trigger device, as seen in FIG. 1. There is no opening through which additional fasteners 30 could be introduced or to which an extra cartridge could be coupled. In DiGiovanni, a cartridge mounted to the existing cartridge would either interfere with the operation of the moving track 120 (see FIG. 2), or with a jaw 14 of the ligating device (see FIG. 6).

Furthermore, the Woods reference discloses the ligature containers 80 as mounted to the discharge end of the device so that ligatures are directly withdrawn from a container and discharged from the device. See, e.g., Woods FIGS. 6-7. The claims of the present application concern an apparatus for sequentially inserting wafers "into a body space". Consequently, any cartridge of wafers can not be mounted at the discharge end of the device because that end is "adapted to be positioned within the body space", as recited in claim 15. The presence of a cartridge or container at the discharge end, as disclosed in Woods, would render the claimed apparatus non-functional and useless.

Thus, there is nothing in any of the references to suggest replacing the existing "cartridges" disclosed in Person and DiGiovanni with the containers shown in Woods. Moreover, no explanation was offered as to how such a substitution can be made in the Person or DiGiovanni devices. Thus, it is believed that claim 15 as amended is patentable over the Person, DiGiovanni and Woods references, alone or in any combination.

Since claim 15 is patentable, so too are its dependent claims 8-14, 16-19 and new claims 21-23. In addition, Applicants have added new claims 21-23 which depend from claims 11. These claims also benefit from the allowability of independent claim 15. Moreover, claims 21 and 22 recite means for removably

mounting the track assembly to the advancement gun while the cartridge is coupled to the track assembly. As explained above, neither the Person nor the DiGiovanni references show a cartridge mounted on the existing cartridge. The cartridge in Person is not removably mounted to the advancement gun. While the cartridge in DiGiovanni is removably mounted, it does not include another cartridge mounted thereon, nor is there any suggestion to do so. While the Woods patent shows removable containers, those containers are mounted directly to the advancement gun and not to a separately removably mounted track. There is nothing in any of these references, alone or in combination, which discloses each limitation of new claims 21 and 22.

New claim 23 parallels original claim 13 in the definition of the linkage coupling the trigger to the advancement mechanism. This claim further recites that this linkage engages the advancement mechanism when the track assembly is mounted to the advancement gun. This feature is not found in any of the cited references, for the reasons explained above with respect to claims 21 and 22.

In view of the foregoing amendments and arguments, it is believed that the present application, including claims 8-19 and 21-23, is in condition for allowance. Action toward that end is earnestly requested.

Respectfully submitted,

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